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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|-----------------|----------------------|---------------------|------------------|--|
| 10/683,537 | 10/09/2003 | Todd Allen Berg | 293/034 Div2 2610 | | |
| 1473 | 7590 12/17/2004 | · | EXAMINER | | |
| FISH & NEAVE LLP 1251 AVENUE OF THE AMERICAS | | | SNOW, BRUCE EDWARD | | |
| 50TH FLOO | | | ART UNIT | PAPER NUMBER | |
| NEW YORK, NY 10020-1105 | | | 3738 | | |

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | A | Applicant(s) | , | | | |
|--|--|--|--|--|---------------|--|--|--|
| Office Action Summary | | 10/683,537 | | BERG ET AL. | | | | |
| | | Examiner | | Art Unit | | | | |
| | | Bruce E Snow | 3 | 738 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| A SHO THE M - Extensi after SI - If the p - If NO p - Failure Any rep | RTENED STATUTORY PERIOD FOR RE AILING DATE OF THIS COMMUNICATIO ions of time may be available under the provisions of 37 CFF X (6) MONTHS from the mailing date of this communication eriod for reply specified above is less than thirty (30) days, a eriod for reply is specified above, the maximum statutory per to reply within the set or extended period for reply will, by stoly received by the Office later than three months after the m patent term adjustment. See 37 CFR 1.704(b). | N. R 1.136(a). In no event, howe reply within the statutory mini riod will apply and will expire S atute, cause the application to | wer, may a reply be timely mum of thirty (30) days w SIX (6) MONTHS from the become ABANDONED (| r filed ill be considered timely mailing date of this co (35 U.S.C. § 133). | | | | |
| Status | | | | | | | | |
| 2a)⊠ T 3)□ S | Responsive to communication(s) filed on <u>06 October 2004</u> . This action is FINAL . 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositio | n of Claims | | | | | | | |
| 4; 5)□ C 6)⊠ C 7)⊠ C | 4) Claim(s) 40-58 and 102-107 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 40-49,51-55,57,58 and 102-107 is/are rejected. 7) Claim(s) 50 and 56 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Applicatio | n Papers | | | | | | | |
| 10) TI | the specification is objected to by the Example drawing(s) filed on is/are: a) applicant may not request that any objection to Replacement drawing sheet(s) including the corple oath or declaration is objected to by the | accepted or b) obje the drawing(s) be held i rection is required if the | n abeyance. See 3 drawing(s) is objec | 7 CFR 1.85(a). ted to. See 37 CF | • • | | | |
| Priority un | der 35 U.S.C. § 119 | | | | | | | |
| a) 1 2 3 | cknowledgment is made of a claim for fore All b) | ents have been recei ents have been recei priority documents ha reau (PCT Rule 17.2) | ved. ved in Application ve been received a)). | No | Stage | | | |
| Attachment(s | ;) | | | | | | | |
| 1) Notice (2) Notice (3) Informa | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449 or PTO/SB | /08) 5) ☐ ! | nterview Summary (P Paper No(s)/Mail Date. Notice of Informal Pate Other: | · |)-152) | | | |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 10/6/04 have been fully considered.

Applicant's amendments overcame the rejections in view of Sachdeva et al (5,885,258) and Simon (5,741,297).

Regarding the rejection in view of Huebsch et al, the Examiner's position is incorporated into the grounds of rejection below.

The rejection in view of Lock et al has been withdrawn, upon further review, it is unclear if Lock et al teaches a medial tubular portion.

Allowable Subject Matter

Claims 50 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 40-45, 47-49, 51-55, 57, and 102-107 are rejected under 35 U.S.C. 102(e) as being anticipated by Huebsch et al (5,853,422).

Huebsch et al teaches a plug for use in plugging an aperture through a patient's body structure comprising: a medial tubular portion 18; a plurality of resilient nitinol fingers 22 integral with the medial tubular portion and radially out from an axial end of and the medial tubular portion; and a plugging structure substantially occluding the medial tubular portion (see at least figure 6). Note the

Note barbs 70.

Regarding the web, see column 4, lines 25-27.

Regarding claim 40 requiring the "medical tubular portion having perforations that enable the medial portion to change in circumference", the Examiner notes the teaching, "the configuration of the metal device may be solid, braided, or woven." See column 4, lines 1-2. It is the Examiner's position that either the braided or woven configuration would have perforations. Additionally, a braided or woven configuration

Application/Control Number: 10/683,537

Art Unit: 3738

would inherently allow for some change in circumference. See Kotula et al (5,725,552) teaching braided or woven is know in the art.

Regarding claims 55 and 102, the "free end" is interpreted as the end with the hinge point 24. See figure 24.

Regarding new claims 105-107, note at least column 4, lines 32 et seq. teaching the hinge point 24 of the resilient fingers by thinning or a tapered groove 20 which produces a finger with a varied width as required in claim 107. It is the Examiner position that these configurations would produce "each finger has different flexural stiffness at different points along its length."

Regarding claim 103, a braided or woven configuration is interpreted as being a "single hollow tube of material".

Claim 51, the figures overlap when viewed from an axial end.

Claims 40, 42-49, 51-55, 57-58, 102-107 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanson et al (6,113,612).

Referring to all figures, specifically figure 6 for discussion, Swanson et al teaches a plug for use in plugging an aperture through a patient's body structure comprising: a medial tubular portion 10 having perforations to enable a change in circurcumference; a plurality of resilient fingers 42 integral with the medial tubular portion and radially out from an axial end of and the medial tubular portion; and a plugging structure (balloon catheter) substantially occluding the medial tubular portion.

Regarding claims 52-54 and 106-107, see at least 12:14 et seq. teaching the fingers can be spikes which inherently taper in both width and thickness. See all figures.

Claim 46, see at least figure 25.

Claim 51, the figures overlap when viewed from an axial end.

Regarding claim 57, see web structure 530 teaching silicone. See 13:15 et seq.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al (5,853,422).

Huebsch et al teaches the plug as described above and teaches an elastic web however, fails to teach silicone. Silicone is also well known in the art as an elastic polymer and would have been obvious to one having ordinary skill in the art to have used it for the elastic web of Huebsch et al for its elasticity and biocompatibility.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (6,113,612).

Swanson et al teaches the plug as described above, however, fails to teach it constructed from nitinol. It would have been obvious to one having ordinary skill in the art to have utilized nitinol for its well know biocompatibility and use in the vasculature.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW PRIMARY EXAMINER